

Serial No. 10/662,008  
Attorney Docket No. PG3411US2

## REMARKS

Claims 1-20 are pending. Applicants address below each of the rejections set forth in the Action.

### I. Claims 1-20 Are Patentable over Britto in view of Chippendale

Claims 1-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,253,762 to Britto (Britto) in view of U.S. Patent No. 5,490,497 to Chippendale, et al. (Chippendale). Applicants respectfully traverse this rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.<sup>1</sup> M.P.E.P. § 2142. Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness for at least the reason that, even if combined, Britto and Chippendale do not teach or suggest all of the claim recitations.

For example, claim 1 recites an aerosol container that comprises:

a vial body containing an aerosol formulation of a suspension or solution of a medicament in a hydrogen-containing fluorocarbon liquid propellant, and  
a valve for dispensing a metered amount of the aerosol formulation per actuation thereof,

wherein the valve comprises a valve body defining a metering chamber configured to contain a metered amount of the aerosol formulation for dispensing by the valve, a transfer passage through which the metered amount of the aerosol formulation is able to pass from the vial body into the metering chamber, and dispensing means which enables the metered amount of the aerosol formulation to be dispensed from the metering chamber; and

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<sup>1</sup> Because all three criteria must be met in order to establish a *prima facie* case of obviousness, and the criterion that the prior art references when combined must teach or suggest all the claim limitations has not been met, Applicants address this criterion without discussion of the other two criteria, namely whether there is a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings and whether there is a reasonable expectation of success. Applicants' decision not to discuss these other two criteria is in no way an acquiescence that these criteria have been proven by the Patent Office, and Applicants expressly reserve the right to address one or both of these criteria in future responses, should the need arise.

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wherein the metering chamber is made from a plastics material which is a mixture of a fluorinated polymer and a non-fluorinated polymer.

Britto in combination with Chippendale neither discloses nor suggests an aerosol container as recited in claim 1. For example, Britto in combination with Chippendale neither discloses nor suggests an aerosol container that includes a valve having a metering chamber “wherein the metering chamber is made from a plastics material which is a mixture of a fluorinated polymer and a non-fluorinated polymer” as recited in claim 1.

At most, Britto provides a general description of materials that can be used in metering valves. Specifically, at column 4, lines 55-62, Britto states:

The drug metering valve consists of parts usually made of stainless steel, a pharmacologically inert and propellant resistant polymer, such as acetal, polyamide (e.g., Nylon®), polycarbonate, polyester, fluorocarbon polymer (e.g., Teflon®) or a combination of these materials. Additionally, seals and “O” rings of various materials (e.g., nitrile rubbers, polyurethane, acetyl resin, fluorocarbon polymers), or other elastomeric materials are employed in and around the valve.

Thus, Britto proposes that metering valves consists of parts without specifically naming the parts of the valve, and proposes that these parts are usually made of various materials, without noting the particular material or materials that would be used for a particular valve part. Moreover, while Britto does state that “a combination of materials” can be used, one of ordinary skill in the art, using common general knowledge, would understand the first sentence quoted above as proposing that a combination of the listed materials may be used in the metering valve as a whole, not in a single valve part. In other words, one of the valve parts could be made from one of the listed materials, e.g. stainless steel, while another valve part could be made from another of the listed materials, e.g. acetal. The general description provided in Britto does not disclose or suggest a metering chamber made from a plastics material which is a mixture of a fluorinated polymer and a non-fluorinated polymer as recited in claim 1.

Chippendale does not make up for the shortcomings of Britto. In fact, Chippendale apparently provides no general or specific description of the materials of construction of a metering valve.

Accordingly, when combined Britto and Chippendale fail to disclose or suggest an aerosol container as recited in claim 1. For at least this reason, Applicants respectfully submit that claim 1 is patentable over Britto in view of Chippendale. For at least similar reasons,

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Applicants respectfully submit that independent claim 12 is patentable over Britto in view of Chippendale.

Claims 2-11 each depend from patentable independent claim 1. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicants respectfully submit that these dependent claims are also patentable over Britto in view of Chippendale. Applicants expressly reserve the right to argue the separate patentability of one or more of these claims in the future.

Claims 13-20 each depend from patentable independent claim 12. For at least this reason and without acquiescing in the Action's rejections of these claims, Applicants respectfully submit that these dependent claims are also patentable over Britto in view of Chippendale. Applicants expressly reserve the right to argue the separate patentability of one or more of these claims in the future.

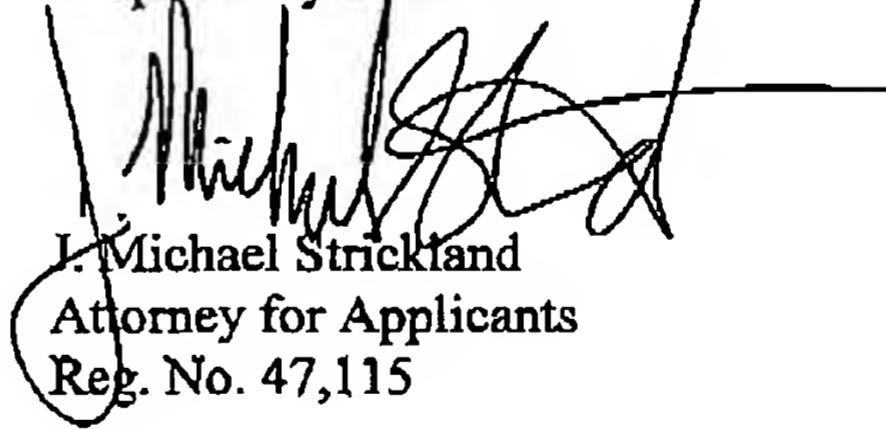
For at least the foregoing reasons, Applicants respectfully request the withdrawal of the outstanding rejections of claims 1-20 over Britto in view of Chippendale.

## II. Conclusion

The concerns of the Examiner addressed in full, Applicants respectfully request the withdrawal of the outstanding rejections and the issuance of a Notice of Allowance forthwith.

Applicants encourage the Examiner to direct any questions regarding this application to the undersigned, who may be contacted at (919) 483-9024.

Respectfully submitted:



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